

REMARKS

Applicant respectfully requests reconsideration of the present application. At the time the Examiner mailed the Final Office Action claims 28-35, 37-44 and 55-59 were pending. By way of the present response, no claims have been amended, no claims have been canceled, and no new claims have been added.

Claim Rejections - 35 U.S.C. § 103

The Examiner has rejected claims 28-35, 37-44 and 56-58 under 35 U.S.C. § 103(a) as being unpatentable over *Saadat et al.*, (U.S. Patent No. 5,935,137) in view of *Berhow et al.* (U.S. Publication No. 2003/0135198). The Examiner has rejected claim 55 under 35 U.S.C. § 103(a) as being unpatentable over *Saadat et al.*, in view of *Berhow et al.* as applied to Claim 28, and further in view of *Shepherd et al.* (U.S. Patent No. 3,566,874). The Examiner has rejected claim 59 under 35 U.S.C. § 103(a) as being unpatentable over *Saadat et al.*, in view of *Berhow et al.* as applied to Claim 28, and further in view of *Peters* (U.S. Patent No. 5,441,485).

Applicant teaches and claims in independent claim 28 a system for delivering a contraceptive device within a fallopian tube, the system comprising, *inter alia*, “at least one coil disposed along the catheter body and encircling the lumen, wherein the whole of the coil is disposed nearer the distal end of the catheter body than the proximal end of the catheter body and extends along the distal portion and the proximal portion; and wherein the distal portion has varying degrees of flexibility determined by constraining the coil within an outer layer of varying thickness or durometer rating along the length of the coil extending along the distal portion.” It is respectfully submitted that the combination of references does not disclose or suggest each and every feature of independent claim 28.

It is Applicant’s understanding that *Saadat et al.* discloses a tubular fallopian sterilization device. *Saadat et al.* does not disclose or suggest constraining a coil within an outer layer of varying thickness or durometer rating along the length of the coil extending along a distal portion of the catheter as is taught and claimed by Applicant in independent claim 28.

With regard to *Berhow et al.* the Examiner states on page 3 of the Office Action that:

Berhow teaches a medical catheter (10) having a coil (16) which extends along the length of the catheter from the distal end (13) to the proximal end (12) where along the catheter (10) the flexibility of the changes for the purpose of having a reinforced catheter with resistance to kinking that may result in trauma to the patient (Figures 1-4A, Paragraphs 0061 and 0071). Further, Berhow discloses outer layer (17) of the lumen (15) constrains the coil (16) and is made of varying durometers (hardness) along its length representative of changes in flexibility. (Paragraphs 0062 and 0063).

In response, Applicant firstly points out that *Berhow et al.* describes reinforcing member (16) as extending along the length of the catheter from the distal end (13) to the proximal end (12). Thus, **the whole of reinforcing member (16) is not disposed nearer the distal end (13) of the catheter body than the proximal end (12) of the catheter body.**

Additionally, as described in paragraph [0051] “the reinforcing member (16) may be terminated proximal to the distal end of the catheter shaft, and a spiral reinforcing member (a helical coil of flat or round material) can be manually slid into its place.” This is additionally illustrated in FIG. 5, where a coiled portion (46a) is slid into place. As described with regard to FIG. 5, **the distal segment 40A of the catheter which extends along the length of the coiled portion 46a does not have a varying hardness or thickness.**

Therefore, the coiled portion (46a) is not within an outer layer of varying thickness or durometer rating along the length of the coil extending along a distal portion of the catheter as is taught and claimed by Applicant in independent claim 28.

It is Applicant’s understanding that *Shepherd et al.* discloses catheters provided with a coating of a hydrophilic acrylate or methacrylate polymer. Applicant respectfully submits that *Shepherd et al.* fails to remedy the deficiencies of *Saadat et al.* and *Berhow et al.* discussed above.

Claims 29-35, 37-44 and 56-58 depend directly or indirectly upon independent claim 28 and are patentable for at least the same reasons. In view of the foregoing amendment and remarks, Applicant respectfully submits that the pending claims are in condition for allowance

and requests the withdrawal of the rejections of claims 28-35, 37-44 and 56-58 under 35 U.S.C. § 103(a).

With regard to claim 56, the Examiner states that “Berhow teaches the medical catheter is most flexible (or least hard) at the distal end and increasingly becomes less flexible (or more hard) towards the proximal end (12). (Paragraph 0061).” Applicant respectfully submits, in view of the above discussion, *Berhow et al.* does not disclose or suggest “an outer layer having varying durometer ratings **along the length of the coil extending along the distal portion**” as required in claim 56. As discussed above, the whole of reinforcing member (16) is not disposed nearer the distal end than the proximal end of the catheter body, and the distal segment 40A does not have varying durometer ratings along the length of coiled portion (46a). Accordingly, Applicant respectfully requests the withdrawal of the rejection of claim 56 under 35 U.S.C. § 103(a) in addition to the reasons provided for independent claim 28.

With regard to dependent claim 57, the Examiner states that “Berhow teaches a tapered region (32) and a lumen (15) that extends throughout the catheter (10). (Paragraph 0038).” Applicant respectfully points out that the tapered region (32) is **in the distal portion, not the proximal portion of the catheter**. Additionally, the tapered region (32) is part of the catheter (30) wall, and the **lumen (15) is not tapered**. Therefore, *Berhow et al.* does not disclose or suggest “the lumen includes a tapered region where the lumen extends through the proximal portion” as is taught and claimed by Applicant in claim 57. Accordingly, Applicant respectfully requests the withdrawal of the rejection of claim 57 under 35 U.S.C. § 103(a) in addition to the reasons provided for independent claim 28.

With regard to dependent claim 59, it is Applicant’s understanding that *Peters* discloses a bladder catheter including a stiff inner tube 10 which is surrounded by an inflatable sheath, which is inflated to seal the urethra after insertion. The inflatable sheath can be formed with sections of varying stiffness, obtained by varying the thickness, so that a plurality of circumferentially

spaced flexible sections 24 inflate to form a plurality of circumferentially spaced retention balloons 26.

The Examiner states that “it would have been obvious to one having ordinary skill in the art to modify the catheter manufacturing method for imparting flexibility of the modified Saadat, to include the alternative catheter manufacturing method of varying the thickness of the catheter, as taught by Peters as an alternative method by which the catheter can have varying degrees of flexibility along its length.” Applicant respectfully disagrees, and submits that one of ordinary skill in the art would not have been motivated to further modify the modified *Saadat et al.* which includes the outer jacket 17/40 of *Berhow et al.* placed over reinforcing member 16 in view of the inflatable sheath of *Peters*. *Berhow et al.* and *Peters* do not suggest the combination with each other, nor is it apparent why one of ordinary skill in the art would modify the flexible outer jacket 17/40 of *Berhow et al.*, which is designed for kink resistance, to have the variable thickness of *Peters* which is used to form a plurality of circumferentially spaced retention balloons 26 that expand against the patient’s anatomy and seal the urethra.

Accordingly, Applicant respectfully requests the withdrawal of the rejection of claim 59 under 35 U.S.C. § 103(a) over *Saadat et al.* in view of *Berhow et al.* and *Peters* in addition to the reasons provided for independent claim 28.

In view of the foregoing amendments and remarks, Applicant respectfully submits that the pending claims are in condition for allowance.

Please charge any shortages and credit any overages to Deposit Account No. 02-2666. Any necessary extension of time for response not already requested is hereby requested. Please charge any corresponding fee to Deposit Account No. 02-2666.

Respectfully submitted,

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